PCT/EP 99/09614

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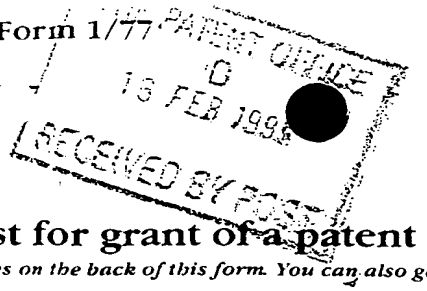

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Request for grant of a patent

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Cardiff Road
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1. Your reference

CGP/PG3605

2. Patent application number
(The Patent Office will fill in this part)

16 FEB 1999

9903342.5

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

GLAXO GROUP LTD
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UNITED KINGDOM

Patents ADP number *(if you know it)*

4 7358703

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

INHALATION DEVICE

5. Name of your agent *(if you have one)*

DR CHRISTOPHER G PIKE

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

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Patents ADP number *(if you know it)*

7497928001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
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Continuation sheets of this form	0
Description	8
Claim(s)	3
Abstract	1
Drawing(s)	2 + 2

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Priority documents	
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Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 15 FEB 1999

DR C G PIKE – AGENT FOR THE APPLICANT

12. Name and daytime telephone number of person to contact in the United Kingdom DR C G PIKE 01628 471869

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Inhalation device

The present invention relates to a medicament carrier for use in an inhalation device for use in the administration of medicament to a patient. The carrier comprises a conveniently storable elongate tape having a plurality of medicament retainers thereon.

The use of inhalation devices in the administration of medicaments, for example in bronchodilation therapy, is well known. Such devices generally comprise a body or housing within which a medicament container is located. A mouthpiece (or nozzle) is typically provided, wherein 'in use' the mouthpiece communicates with the medicament container to allow passage of medicament from the source to the mouthpiece and thence, to the patient.

In a typical dispensing operation the body of the device is held by the patient and the mouthpiece (or nozzle) of the inhalation device is placed in the mouth (or nose) of the patient. The patient inhales, thereby causing transfer of medicament from the medicament container to the interior of the body of the patient.

It is desirable that the inhalation device is able to provide a plurality of doses of medicament. Known devices include metered dose inhalers having an aerosol container comprising sufficient medicament to provide plural individual doses. Also known are dry powder inhalers having a reservoir of dry powder from which individual doses may be delivered.

Other known devices have a medicament carrier having plural individual medicament retainers thereon. One such carrier is shaped in the form of a rigid disc having plural medicament-containing blisters arranged in a circular configuration thereon. Typically, such discs are designed to provide from five to ten doses. Another such carrier has an elongate tape carrier having plural medicament-containing blisters arranged in a line along the length of the tape. The tape is generally retained on a spindle and the tape is progressively

unwound from the spindle to allow access to individual blisters. Typically, such tape carriers are designed to provide about forty to sixty doses.

There is continuing interest in the design of medicament carriers capable of providing very large numbers of individual doses. However, there is also a desire to reduce the size of the device, and hence the carrier, so that it is readily portable by the patient. It will be appreciated that with the above described known carriers increasing the number of doses will also result in an inevitable and undesirable increase in the required size of disc and tape-winding on the spindle.

The Applicants have now found that the use of a medicament carrier comprising an elongate carrier having a plurality of individually accessible medicament retainers, wherein the carrier is storable in a flat spiral configuration and extendable for dispensing as a helix, allows for the provision of large numbers of doses from a single carrier, whilst enabling the size of the carrier and device to be kept at an acceptable level.

WO95/16483 describes an inhalation device comprising a housing which houses a cylindrical container. The container has a number of helically arranged compartments, each of which contains a dose of powdered medicament. To allow for dosing of medicament, the container is rotated thereby bringing bringing a compartment into communication with an airway. The airway communicates with an air inlet through which the patient inhales, which inhalation causing passage of medicament from the compartment through the airway to the air inlet.

According to one aspect of the present invention there is provided a medicament carrier for use in an inhalation device comprising an elongate carrier having a plurality of medicament retainers, wherein said elongate carrier is storable in a flat spiral configuration and extendable as a helix.

Preferably, the medicament retainers are serially arranged along the elongate carrier. The elongate carrier is, for example a tape carrier.

Preferably, each medicament retainer comprises a cavity in the elongate carrier. Typically, a seal is provided to each cavity. More preferably the seal comprises a sealing tape and each cavity is individually accessible by peelable removal of the sealing tape.

The medicament retainers are sized and shaped for retention of medicament. Each retainer may for example, be a medicament-retaining pocket. Suitable pocket forms include a cavity (recess) provided in the retainer, a cup having side walls standing proud from the carrier and any composite of these cavity/cup forms. A cover, preferably a hermetically sealing cover may be provided to the pocket.

The retainer may also for example, be a hole in the retainer. Optionally the hole has free-standing walls provided therearound. Ther hole may also optionally be provided with a mesh arrangement therein. The mesh may be formed of any suitable materials including plastic materials. Covers, preferably hermetically sealing covers may be provided to seal the hole.

Preferably, each medicament retainer is sized to retain a single dose of medicament.

Preferably, the medicament carrier has from 60 to 500, preferably from 100 to 300, medicament retainers.

In use one or more of the medicament retainers are charged with medicament.

According to another aspect of the present invention there is provided a medicament carrier for use in an inhalation device comprising an elongate carrier having a plurality of medicament doses thereon, wherein said elongate carrier is storable in a flat spiral configuration and extendable as a helix.

The medicament doses may be applied to the carrier by any suitable method including wet and dry printing methods. Suitable wet printing methods include ink jet printing. Suitable dry printing methods include xerographic and electrostatic printing methods.

According to a further aspect of the present invention there is provided an inhalation device comprising

a housing having an air inlet, an air outlet and an airway therebetween;

an elongate carrier having a plurality of medicament retainers, wherein said elongate carrier is storable in a flat spiral configuration; and

a mover in communication with the elongate carrier for helically extending the elongate carrier such as to successively move each medicament retainer to an access position.

Preferably, each medicament retainer comprises a cavity in the elongate carrier.

Preferably, each medicament retainer has a seal, the device additionally comprising an actuator for unsealing a medicament retainer at the access position.

In one aspect, the seal comprises a sealing tape arranged along the elongate carrier and wherein each successive cavity is accessible by peelable removal of the tape from the elongate carrier. More preferably, an end of said sealing tape connects to the actuator and peelable removal of the sealing tape is achievable by movement of the actuator relative to the elongate carrier.

Preferably, the mover is rotatable relative to the housing such that rotation of the mover results in coiling of the elongate carrier around the mover, and also said actuator is rotatable relative to the housing such that rotation of the actuator results in coiling of the tape around the actuator.

Preferably, the mover is an axially mounted tapered pole and the actuator is also an axially mounted tapered pole.

In another aspect, the actuator comprises a piercer for piercably unsealing a medicament retainer.

According to a still further aspect of the present invention there is provided an inhalation device comprising

a housing having an air inlet, an air outlet and an airway therebetween;

an elongate carrier having a plurality of doses thereon, wherein said elongate carrier is storable in a flat spiral configuration; and

a mover in communication with the elongate carrier for helically extending the elongate carrier such as to serially move each dose to an access position.

Preferably, the air outlet is provided with a mouthpiece. Herein the term 'mouthpiece' is used in a generic sense to mean an element shaped such as to be insertable into the mouth or nose of a patient for inhalation therethrough.

Preferably, the device is provided with a dose counter, which indicates the number of doses dispensed from or remaining in the container. More preferably, the dose counter comprises an indexing mechanism actuated by a predetermined movement of the medicament container relative to the body.

Preferably, the medicament is in dry-powder form.

According to a still further aspect of the present invention there is provided the use of an inhalation device as described herein for the administration of medicament to a patient.

Preferred embodiments of the present invention will now be described with reference to the accompanying drawings in which:

Fig. 1 is a view of a medicament carrier in accord with the present invention in the flat spiral storage configuration; and

Fig. 2 is a view of the medicament carrier of Fig. 1 in the helically extended configuration;

Fig. 3 is an exploded view of a medicament cartridge suitable for containing a medicament carrier in accord with the present invention;

Fig. 4 is a view of the medicament cartridge of Fig 3. in assembled form and loaded with a medicament carrier.

Fig. 1 shows a medicament carrier in the form of a tape 10 arranged in a flat spiral storage configuration. The tape 10 is provided with a plurality of medicament retaining cavities 12. The leading end 14 of the tape is shown extended from the storage configuration making it available for feeding into an access station of an inhalation device (not shown) where the medicament retainers 12 may be successively accessed. An airway will link the access station to a mouthpiece through which the patient inhales, thereby enabling inhalation of mediacment.

Fig 2. shows the medicament carrier tape of Fig 1 with the tape 10 near fully expanded from the flat spiral storage configuration into a helical configuration.

In one aspect, the tape 10 is housed in the storage configuration in a flat circular medicament cartridge which is loadable into an inhalation device for dispensing therefrom. Fig 3. shows an exploded view of a suitable flat circular cartridge having a bottom circular cover 20 with peripheral walls 22 extending therearound and a top cover 30. The top cover 30 of the cartridge is provided with an exit slit 32 which is sized and shaped to receive the leading end 14 of the tape 10.

Fig. 4 shows the flat circular cartridge of Fig 3. in assembled form and loaded with a medicament carrier tape. The leading end 14 of the tape protrudes from the exit slit 32 in the top cover 30 of the cartridge. When loaded into an inhalation device, the leading end 14 of the tape is progessively fed into a medicament access station to enable access to successive medicament retainers 12. The inhalation device will typically include a drive mechanism connected to the leading end 14 of the tape 10 to drivably encourage the tape

towards the medicament access station. The drive mechanism may be manually actuable or it may be powered electrically.

The medicament carrier, cartridge and inhalation device herein is suitable for dispensing medicament, particularly for the treatment of respiratory disorders. Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or nedocromil; antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti- inflammatories, e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone acetonide; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro-α-[[[6-[2-(2-pyridinyl)ethoxy] hexyl]methyl] benzenemethanol; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclometasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate).

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

CLAIMS:

1. Medicament carrier for use in an inhalation device comprising an elongate carrier having a plurality of medicament retainers, wherein said elongate carrier is storable in a flat spiral configuration and extendable as a helix.

2. Medicament carrier according to Claim 1, wherein said medicament retainers are serially arranged along the elongate carrier.

3. Medicament carrier according to either of Claims 1 or 2, wherein each medicament retainer comprises a cavity in the elongate carrier.

4. Medicament carrier according to Claim 3, wherein a seal is provided to each cavity.

5. Medicament carrier according to Claim 4, wherein said seal comprises a sealing tape and each cavity is individually accessible by peelable removal of the sealing tape.

6. Medicament carrier according to any of Claims 1 to 5, wherein each medicament retainer is sized to retain a single dose of medicament.

7. Medicament carrier according to any of Claims 1 to 6, having from 60 to 500, preferably from 100 to 300, medicament retainers.

8. Medicament carrier according to any of Claims 1 to 7, wherein medicament is present in one or more of the medicament retainers.

9. Medicament carrier for use in an inhalation device comprising an elongate carrier having a plurality of medicament doses thereon, wherein said elongate carrier is storable in a flat spiral configuration and extendable as a helix.

10. Medicament carrier according to Claim 9, wherein the medicament doses are applied to the carrier by wet or dry printing methods.

11. Inhalation device comprising

a housing having an air inlet, an air outlet and an airway therebetween;

an elongate carrier having a plurality of medicament retainers, wherein said elongate carrier is storable in a flat spiral configuration; and

a mover in communication with the elongate carrier for helically extending the elongate carrier such as to successively move each medicament retainer to an access position.

12. Inhalation device according to Claim 11, wherein each medicament retainer comprises a cavity in the elongate carrier.

13. Inhalation device according to Claim 12, wherein each medicament retainer has a seal, the device additionally comprising

an actuator for unsealing a medicament retainer at the access position.

14. Inhalation device according to Claim 13, wherein said seal comprises a sealing tape arranged along the elongate carrier and wherein each successive cavity is accessible by peelable removal of the tape from the elongate carrier.

15. Inhalation device according to Claim 14, wherein an end of said sealing tape connects to said actuator and peelable removal of the sealing tape is achievable by movement of the actuator relative to the elongate carrier.

16. Inhalation device according to Claim 15, wherein said mover is rotatable relative to the housing such that rotation of the mover results in coiling of the elongate carrier around the mover, and wherein said actuator is rotatable relative to the housing such that rotation of the actuator results in coiling of the tape around the actuator.

17. Inhalation device according to Claim 16, wherein the mover is an axially mounted tapered pole and the actuator is also an axially mounted tapered pole.

18. Inhalation device according to Claim 13, wherein said actuator comprises a piercer for piercably unsealing a medicament retainer.

19. Inhalation device comprising

a housing having an air inlet, an air outlet and an airway therebetween;

an elongate carrier having a plurality of doses thereon, wherein said elongate carrier is storable in a flat spiral configuration; and

a mover in communication with the elongate carrier for helically extending the elongate carrier such as to serially move each dose to an access position.

20. Inhalation device according to any of Claims11 to 19, wherein said air outlet is provided with a mouthpiece.

21. Use of an inhalation device according to any of Claims 11 to 20 for the administration of medicament to a patient.

Abstract

There is provided a medicament carrier for use in an inhalation device comprising an elongate carrier having a plurality of medicament retainers, wherein the elongate carrier is storable in a flat spiral configuration and extendable as a helix.

There is also provided an inhalation device comprising a housing having an air inlet, an air outlet, an airway therebetween and an elongate carrier having a plurality of medicament retainers. The elongate carrier is storable in a flat spiral configuration. The device also comprises a mover in communication with the elongate carrier for helically extending the elongate carrier such as to successively move each medicament retainer to an access position.

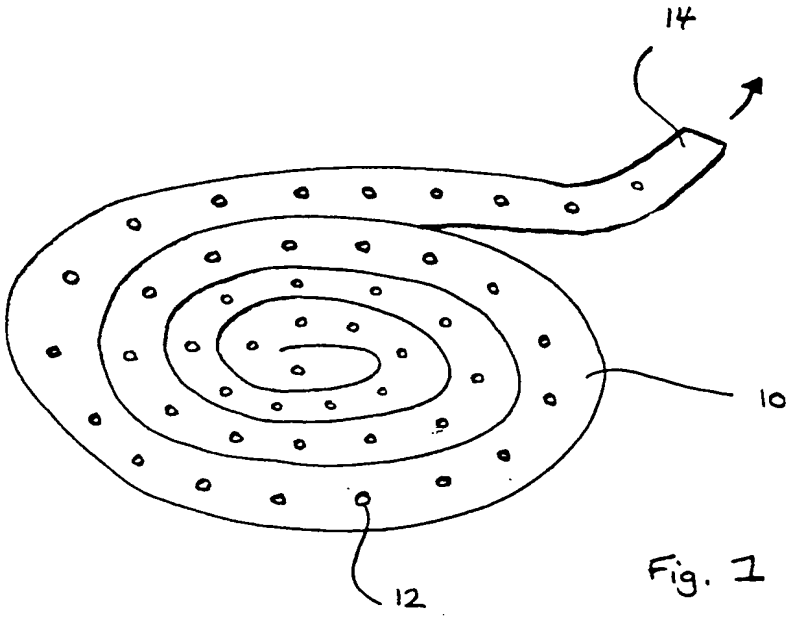

Fig. 1

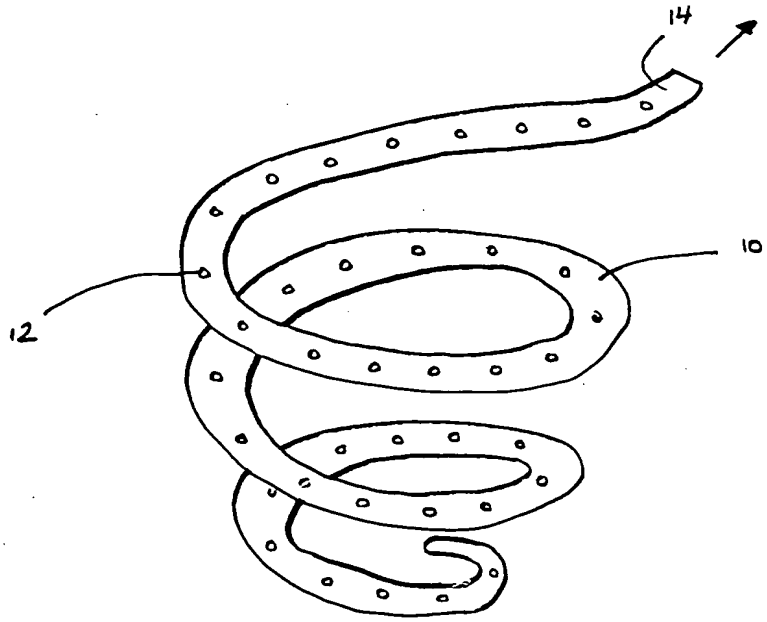

Fig. 2

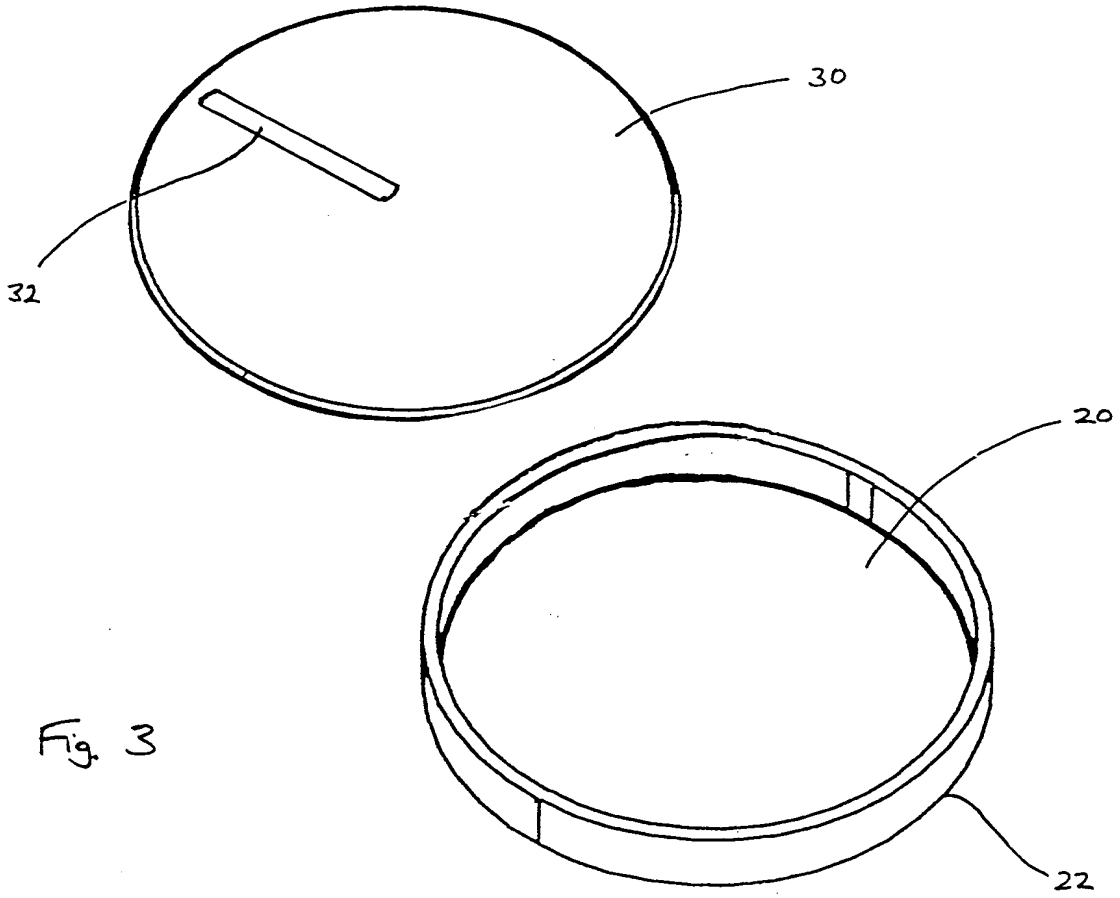

Fig. 3

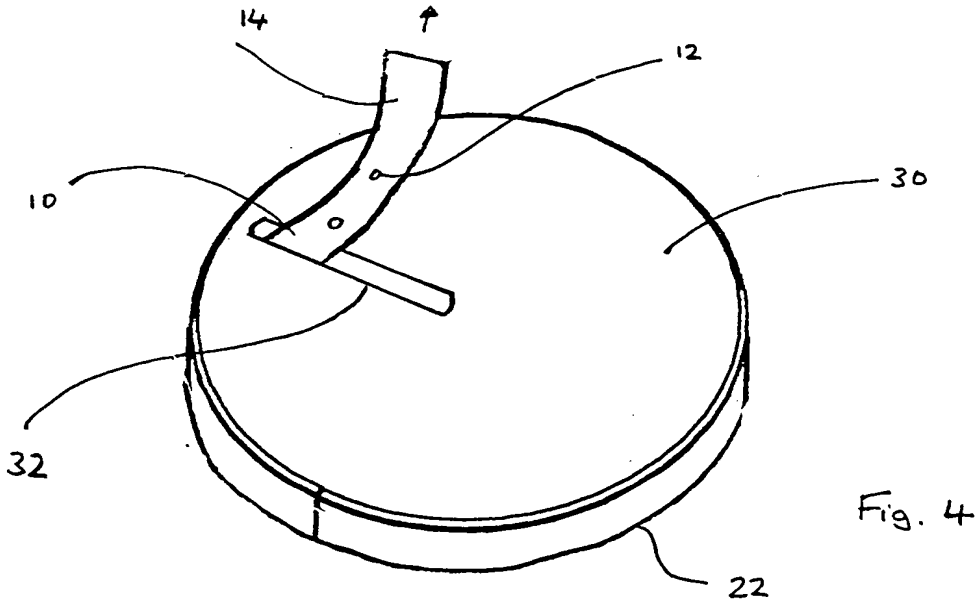

Fig. 4